National Institute for Health and Care Excellence

Skin cancer: the VivaScope 1500 and 3000 systems for detecting and monitoring skin lesions

Diagnostics Assessment Report (DAR) - Comments

Please try to ensure that, where possible, comments do not compromise the identity of individuals or organisations

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Organisation: British Association of Dermatologists

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Thank you for the opportunity to comment on this draft assessment report (systematic review) on VivaScope 1500 and 3000. The aforementioned sub-committees of the British Association of Dermatologists have reviewed the report and have a number of concerns as outlined below:			
1.	**General**		It is unclear why there was selection of this particular confocal laser scanning microscopy system for review over others, or over a wider assessment of confocal microscopy in general.
2.	**General**		At the workshop, our nominated expert highlighted the need for further evidence on the technology's usefulness as compared against, - well trained or experienced dermatologists' clinical acumen, and - other modalities for skin imaging, before going ahead with the positioning of this particular technology.
3.	**General**		We have also been informed that NICE was aware, following the consultation for the draft scope, of an NIHR programme (in Birmingham) looking at evaluating all diagnostic tests for melanoma and non-melanoma skin cancers through a suite of over 20 systematic reviews.
4.	**General**		Overall, there is very limited evidence available for this systematic review (all observational studies); the evidence for clinically relevant benefits from these technologies over and above standard clinical practice is very weak – an RCT is really required to demonstrate this. It appears very clear that this technology lacks conclusive evidence of benefit so the

		conclusion should be unambiguous and ***not*** to recommend.
5.	**General**	We are most concerned about the ambiguous language used in the conclusions in this systematic review indicating that this tool may be useful, whilst at the same time saying the evidence is lacking. This may be used inappropriately for potential selective quotation (by those with relevant conflicts of interest) to try and persuade the NHS to use scarce resources on an unproven technology, for example: "There is a paucity of randomised controlled trial (RCT) evidence for both diagnostic accuracy and margin delineation with VivaScope 1500 and 3000. However, VivaScope subsequent to dermoscopy ***may improve*** diagnostic accuracy of equivocal skin lesions compared to dermoscopy alone, particularly for malignant melanomas. In terms of margin delineation, VivaScope 1500 mapping for LM and LMM ***may improve*** the accuracy in terms of complete excision of lesions compared with dermoscopically determined margins. In addition, use of VivaScope ***appears to be*** a cost-effective strategy in the diagnostic assessment of suspected skin cancer (more specifically, of suspected melanomas with an equivocal finding in dermoscopy and suspected BCCs with a positive or equivocal finding in dermoscopy) and the margin delineation of lentigo maligna prior to surgical treatment, in particular when VivaScope is used for all three indications considered in the economic analysis."
6.	**General**	The criteria for use of this technology must be appraised very carefully. The rigor of the analysis was low and based on 'crude' health economic data. We would be very interested to learn the funding body for the one, unpublished cost-effectiveness article submitted and later included following relaxation of the pre-determined inclusion criteria.
7.	**General**	At present, this is a very time-consuming technique which may have a significant impact on the number of patients per hour able to be assessed, and consequently lead to an increased waiting list.
8.	**General**	Approval by NICE could potentially give credibility to a still unproven use of the technology.
9.	**General**	We would recommend that NICE investigates the full range of technologies available for diagnostic scanning of the skin, perhaps even including 1) optical cohesive tomography and 2) infrared spectroscopy, and justify why this particular VivaScope system warrants such detailed assessment.
10.	**Conclusion**	We would also recommend that the sentence "However, this research may not be feasible due to the current lack of expertise and availability of VivaScope in the UK" is deleted or reworded. If VivaScope cannot be evaluated in a properly set up multi-centre RCT in the UK, then it will be difficult to see how its introduction into UK-wide dermatology centres could be validated. Proponents of this technology feel it has the potential

		for wider clinical use in the future, once validation is achieved and training courses for dermatologists have been set up.